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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|

| EXAMINER |
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| ART UNIT | PAPER NUMBER |
|---|---|
|  | 6 |

**DATE MAILED:**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

PTO-90C (Rev 11/00)

1- File Copy

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|---|---|---|---|
| ***Office Action Summary*** | **Application No.**<br>09/556,941 | **Applicant(s)**<br>HIECHMAN ET AL. | |
| | **Examiner**<br>Dave Nguyen | **Art Unit**<br>1633 | |

*-- The **MAILING DATE** of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-43* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to an enormous number of protein complexes, readable on class 435, sublass 350.

II. Claims 5 and 6, drawn to an enormous number of antibodies, classified in Class 424, subclass 134.1

III. Claims 1-14, drawn to a diagnostic method for identifying a disorder by measuring the presence and/or binding of any of the disclosed protein complexes in an animal, classified in Class 435, subclass 7.1.

IV. Claims 15-23, drawn to an assaying method for identifying mutation that is useful for diagnostic method by measuring the non-binding of a mutant protein to any of the protein of the disclosed protein complexes, classified in Class 435, subclass 7.1.

V. Claims 24-28, and 40, drawn to a drug screening assay, readable in class 435, subclass 7.1.

VI. Claims 29-36, drawn to transgenic animals, readable on class 800, subclasses 13 and 14.

VII. Claims 37, drawn to an *in vivo* cell, classified in Class 424, subclass 93.2.

VIII. Claim 39, drawn to an *in vitro* cell line, classified in Class 435, subclass 325.

IX. Claim 41-42, drawn to DNA encoding SEQ ID NOS: 4, 6, 8 and 10, classified in Class 536, subclass 23.1.

X. Claims 43, drawn to polypeptide sequences of SEQ ID NOS: 4, 6, 8 and 10, readable on class 435, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods as claimed in Group III, IV and V appear to constitute patentably distinct inventions for the following reasons: Methods cited in inventions III, IV and V are directed to different goal(s) and comprise materially distinct steps that render the methods patentably distinct with respect to their functions and their sites of action.

Groups I, II, VI-X and Groups III-V are patentably distinct because the Groups are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA sequences of Invention IX are not related and/or limited for use any of the claimed methods, the DNA sequences can be used in a gene therapy method or production of recombinant proteins *in vitro;* the antibodies and can be used in DNA vaccination methods. In addition, the polypeptides can be used in protein therapy methods or can be use in any of the respective claimed methods.

Group I-II, and VI-X are distinct from another, because the DNA molecules, the complex of Group I, the polypeptides of Group X , the antibodies of Group II, and the transgenic animals of Group IV, the *in vivo* cell of Group VII, the *in vitro* cell of group VIII, respectively, can be employed for a variety of uses, and are not limited to production of respective products as claimed in the restricted Groups. For example, the DNA molecules of Group IX can be employed in hybridization assays, the protein of Group X can be used in production of antibodies, the antibodies of Group II are not even related to that of Groups VI-X and can be used in vaccination, the protein complexes of Invention I are enormous in the breadth and can be used in diagnostic assays, and none of the product claims as claimed in Group I, II, and VII to X are related or limited to the making of the claimed transgenic animal, as indicated above.

SEQ ID NO: 4;

SEQ IDNO: 6;

SEQ ID NO: 8:

SEQ ID NO: 10.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the specific compound as listed in the claim, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly since it would be unduly burdensome for the examiner to search and examine the claimed inventions as presently claimed in the application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is **(703) 305-3015**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Patent Examiner
Art Unit: 1633

**DAVE T. NGUYEN
PRIMARY EXAMINER**

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| No. | Doccode | Number of pages |
|---|---|---|
| 1 | A... | 1 |
| 2 | REM | 15 |
| 3 | XT/ | 2 |

Total number of pages: 18

Remarks:

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